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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/807,362

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3954

7590

07/03/2008

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EXAMINER

KENNEDY, SHARON E

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

07/03/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/807,362	<b>Applicant(s)</b> GLAUSER ET AL.	
	<b>Examiner</b> Sharon E. Kennedy	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-102 is/are pending in the application.
- 4a) Of the above claim(s) 1-42 and 66-99 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 43 and 44 is/are allowed.
- 6) ☒ Claim(s) 45-65, 100-102 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

This application contains claims 1-42, 66-99 drawn to an invention nonelected without traverse in the reply filed on October 23, 2007. Applicant should consider cancelling these claims in any reply filed to this office action.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 45-65, 102 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 102 is confusing because it further requires an agent which may be combinations of various agents, and claim 100, from which it depends, calls for a generic "bioactive agent". This is confusing. Likely, claim 102 should be amended to depend from claim 101. Claims 45, 53 have the same problem. Regarding claims 56, 59, 64, 65 it is unclear how the biobeneficial moiety modifies the independent claim 43. Is this the same agent or an additional agent? Applicant must carefully characterize the various biobeneficial agents, and what is present or not, to overcome this rejection.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 100-101 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Koulik et al. '788. Claim 100 calls for a biodegradable or nondegradable backbone which may be one of the polymers selected for the long list of polymer supplied. For example, Koulik discloses poly(ethylene glycol) methacrylate in column 6, lines 11-12. This anticipates applicant's claimed "PEG ... groups" from the biodegradable polymer list.

Claims 100-102 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Moussy et al., US 6,497,729. Moussy discloses a tissue implant comprising a bioactive polymer layer (abstract) such as poly(ligands) (column 7, lines 22+, anticipating applicant's claims "amino acids") which may contain bioactive agents (abstract) such as dexamethasone (column 4, line 25). Phosphatidyl choline may be added as a surfactant to ensure polypeptide entrapment within a PLGA microsphere. In the absence of further definition of how the choline or phosphoryl choline moieties are assembled into the biocompatible polymer, the examiner takes the position that the Moussy disclosure meets the broadly claimed invention embodiments.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 102 is rejected under 35 U.S.C. 103(a) as being unpatentable over Koulik '788 in view of Sass, US 6,383,215. Koulik discloses the inclusion of various biomolecules (column 13, lines 6+) which may be hormones, for example (column 13, line 10), but fails to disclose the specifically mentioned drugs, etc., in applicant's claim 102. The Koulik device is useful for blood contacting implants (column 12, lines 58+) such as vascular grafts, stents, etc. (column 12, line 76). Sass is cited to exemplify that the concept of adding estradiol, for example, to stents for implantation into blood vessels is already well known. See the Sass front page. Accordingly, it would be obvious to one of ordinary skill in the art to choose estradiol as the hormone in the Koulik device as shown by Sass since the benefits are already well known.

***Allowable Subject Matter***

Claims 43 and 44 are allowed.

Claims 45-65 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: Claim 43 is directed to a specific implantable coating including phospholipid moieties which must be one of phosphoryl serine, phosphoryl inositol, di-phosphoryl glycerol, zwitterionic phosphoryl ethanolamine and combinations thereof. None of the prior art discloses or suggests these specific phosphoryl moieties. Applicant's specification points out that these are the preferred moieties. Yedgar et al., US 5,064,816, discloses the preferred phosphoryl moieties attached to carrier polymers which may also include beneficial ingredients, however, the final product is characterized not as a coating for an implantable medical device, but may be formulated into suppositories and injectable compositions, functioning as anti-allergics and anti-inflammatories.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon E. Kennedy whose telephone number is 571/272-4948. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571/272-8373.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*/Sharon E. Kennedy/*  
Sharon E. Kennedy  
Primary Examiner  
Art Unit 1615